REMARKS

The claims have been amended in a manner that is believed to distinctly and clearly claim the subject matter that is regarded as applicants' invention. In particular, it is made clear that information decoded from a bar code is used, for example in a look-up table, to ascertain from the identity of the specimen and/or the tests to be conducted, how long to keep a second aliquot portion of the original sample on-board the analyzer. Basically, the present invention ensures that the same patient specimen is tested a second time following a previous first testing if it becomes desirable to re-test or additionally test the same specimen at some time after tests on the first sample aliquot are completed, reported, and analyzed by a physician . . . thereby saving time as well as providing for the exact same patient specimen to be tested.

Specification and Drawing Objections

The specification and/or Figure 1 are objected to because the specification describes Figure 1 as showing the elements of a conventional analyzer and at the same time shows element 50 as inventive. In response, replacement paragraphs are provided in accord with 37 CFR 1.121(b), wherein the term conventional has been deleted, No new matter has been presented.

Claim Rejections –35 USC §112

Claims 7-8 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in a way to convey that at the time of the application, the inventors had possession of the claimed subject matter. The Examiner asserts that the specification does not disclose bar codes with such interactive capabilities as to enable establishing the period of time that the second sample aliquot is retained in the storage compartment after tests in the first sample are completed. This rejection is based on the Examiner's belief that the time period may be variable depending on the test performed on the first sample aliquot.

This rejection is respectfully traversed in lieu of the disclosure in paragraph **[0036]** whereat it is clearly disclosed that:

> Incoming specimens to be tested are identified by reading with a ~~conventional~~ bar code reader 49 bar coded indicia on sample tubes 14 to determine, among other items, a patient's identity, the tests to be performed, if a sample aliquot is desired to be retained and if so, for what period of time.

Furthermore, in paragraph **[0042],** it is disclosed that:

> In this second embodiment, the bar code indicia may also containing instructions that establish the particular period of time that the second sample aliquot is retained in an aliquot storage vessel 43 within environmentally controlled storage compartment 50 after tests on the corresponding first sample aliquot are completed.

From this disclosure, one skilled in the art of encoding datum, such as the period of time that a second sample aliquot is retained in the storage compartment after tests in the first sample are completed, is clearly instructed to simply identify a period of time in a data field in the bar code. Claim 7 in particular, is practiced by simply entering a time period, say 2 days, after the "tests on the first sample aliquot are completed." Applicants remain convinced that routine skill in programming and operating such a complex device as an automated clinical analyzer easily enables one to know when "tests of the first sample are completed" and to associate a predefined time period therewith.

With respect to claim 8, Applicants also remain convinced that routine skill in programming and operating such a complex device as an automated clinical analyzer easily enables one to include a simple look-up table that has information correlating a period of time with tests identified in the indicia. The Examiner's attention is called to paragraph [0043] wherein it is disclosed that:

> In this third embodiment, computer CPU 115 contains a look-up-table in memory that automatically establishes from the analytical tests or groups of tests requested the particular period of time that the second sample aliquot is retained in an aliquot storage vessel 43 within environmentally controlled storage compartment 50 after tests on the corresponding first sample aliquot are completed. For example, if a Standard Metabolic Panel (CHEM 8) including Na, K, Cl, CO2, GLUC, BUN, CREA, and CA is to be performed, the second

sample aliquot may be automatically retained in an aliquot storage vessel 43 for a two week period of time.

If the above comments are unconvincing to the Examiner, Applicants would appreciate the opportunity to provide a Declaration under 37 CFR 1.132 by one skilled in the art of programming and operating an automated clinical analyzer to the effect that disclosure found in the specification and found in originally filed claims 7 and 8 is fully enabling for the subject matter of claims 7 and 8.

Claims 1-10 are rejected under USC 112, second paragraph, as being indefinite concerning the indicia and time period and tests, step sequence, and location of aliquots. In response, claim 1 has been amended to specify that the indicia are bar code indicia, that both first and second aliquot portion are aspirated before tests are conducted on the first aliquot portion and that it is a period of storage time that is identified in the bar code indicia. Support for these amendments may be found in paragraphs **[0041]** and **[0042]**.

Concerning claim 3, it is made clear that the bar code indicia can be used, for example in combination with a look up table, to determine the period of storage time that the second aliquot portion is retained in storage. Support for these amendments may be found in paragraph **[0042]**.

Concerning claims 7 and 8, the Examiner is correct in that bar codes in themselves are not interactive; however, it is well known how to use the information or data encoded in a bar code to identify the tests to be performed on a specimen in order to further ascertain how long an aliquot of specimen is desirably to be stored. Claim 7 has been amended to make it clear that the bar code indicia contains information that can be used to establish the period of time that the second sample aliquot is retained in the storage compartment. Similarly, Claim 8 has been amended to make it clear that the bar code indicia identify tests to be conducted on the specimen and that the identify of the tests are be used to establish the period of time that the second sample aliquot is retained in the storage compartment. Support for these amendments may be found in paragraphs **[0043]** and **[0046]**.

In view of the amendments and the discussion provided above, Applicants believe that it has clearly been established that at the time of filing the instant application, they had possession of the claimed subject matter and that the disclosure is fully enabling for

one skilled in the art of designing and operating automatic clinical analyzers. It is therefore respectfully requested that the rejection of claims 1-10 Claims under 35 USC 112, first and second paragraphs, be withdrawn.

Claim Rejections –35 USC §103

The Examiner is correct in the presumption that the subject matter of the various claims was commonly owned at the time the inventions covered therein were made.

Claims 1-4, 6 and 9-10 are rejected under 35 USC 103(a) as being unpatentable over Mazza (US 5350564) in view of Thorne et al (US 4678752, IDS). The Examiner cites Mazza for disclosing:

> 1) A conveyor system for feeding individual sample tubes held in an individual sample tube carrier and conveying and/or temporarily storing the individual sample tubes as required.
>
> 2) A bar code tag on each sample tube can be read to identify each individual sample.
>
> 3) In the event the test results are not confirmed, the particular sample may be fed back to the analyzer for a second or subsequent testing.
>
> 4) The conveyor with its storage and dwell time feature makes possible the recall to an analyzer of any sample whose test results are not verified as reliable.

It is noted that Mazza's conveyor only temporarily stores a sample until such time as valid test results are reported. There is no disclosure of a key feature of applicants' inventive concept of storing a sample aliquot for a predetermined period of time based on the identity of either the original sample or of the tests to be conducted on the sample.

The Examiner then turns to Thorne's disclosure of providing an expiration date in a bar code associated with reagent solutions and suggests that it would have been obvious to modify Mazza's method by including a time period on a sample for which the samples is to be stored. The rationale behind the Examiner's suggestion is "because the

samples are degrading with time the same way reagents do and become unacceptable for further use." Applicants traverse this suggestion and rationale for the following reasons.

1) Applicants' invention is useful "to ensure that the same patient specimen is tested a second time following a previous first testing" (paragraph [0019], first three lines) "if it becomes desirable to re-test or additionally test a patient's specimen some period of time after tests on the first sample aliquot are completed, reported, and analyzed by a physician . . . thereby saving time as well as providing for the exact same patient specimen to be tested." (paragraph **[0019]**, lines 11-15). The problem being addressed has nothing whatsoever to do with and is totally unrelated to a sample "degrading in time".

2) Samples that are stored in "temperatures between minus 4 degrees Centigrade and plus 20 degrees Centigrade and relative humidity between about 5% and 75%", like maintained in storage compartment 50 (see paragraph **[0037]**) do not degrade over extended periods of time.

Applicants recognize that the Supreme Court's opinion in the recent case *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 550 U. S. ___ (Apr. 30, 2007) concedes that "invention in most, if not all instances, rely upon building blocks long since uncovered, and claimed discoveries almost of necessity, will be combinations of what, in some sense, is already known" (*KSR*, slip op at 15). For this reason, the KSR rulings maintain that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art . . . and that it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." (*KSR*, slip op. at 14 bridging to 15, underlining added for emphasis)

In rejecting claims 1-4, 6 and 9-10 of the present application under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne, the Examiner has suggested that the reason an artesian would combine the teachings of Mazza and Thorne is to avoid re-testing a sample that may be "degrading in time". Such a reason does not apply to the instant invention that seeks to "ensure that the same patient specimen is tested a second time if it becomes desirable to re-test a specimen after tests on the first sample aliquot are completed, reported, and analyzed by a physician . . .

thereby saving time as well as providing for the exact same patient specimen to be tested." There is no basis for considering that a sample might be "degrading in time" when one is seeking to quickly, re-test an original sample by maintaining the sample on-board an analyzer for a sample-specific period of storage time.

The Examiner's reason for combining the teachings of Mazza and Thorne is also faulty because the second sample aliquot portion is stored under conditions that inhibit degrading. Basically, the time required for a sample to degrade, if such is possible and if so, such a degradation time is certainly going to be longer than a storage time specified by one skilled in the art . . . otherwise the artesian would knowingly and willingly be re-testing a deficient sample and re-reporting the results. In other words, it goes without saying that in order to effectively practice the claimed invention, the storage time for the second aliquot portion will be less than the time required for the stored sample to degrade.

KSR further requires that "a court must ask if the improvement is more than the predictable use of prior-art elements according to their established functions." (*KSR*, slip op. at 4, underlining added for emphasis). In making the present rejection, the Examiner has added bar code information relating to the expiration date of a solution (a reagent, or in the instant invention, a patient's specimen) to a stored solution so as to enable an operator to "discard samples which were retained in the storage compartment for a period of time exceeding the expiration time or date. Such a combination is not the same as, nor does such a combination make obvious under KSR the claimed method wherein bar code indicia are provided on the original sample container to indicate a predetermined period of storage time after tests on said first sample aliquot are completed, reported, or analyzed by a physician to allow for re-testing of the patient's specimen (Claim 1), or wherein bar code indicia are provided on the original sample container to indicate the tests to be completed on the patient's sample and using the identity of those tests to determine a storage period of time for a second aliquot portion (Claim 8).

For these several reasons, Applicants respectfully submit that the Examiner has provided an invalid reason for combining Wells and Tomasso and request reversal of the rejection of claims 1-4, 6 and 9-10 as being unpatentable under 35 USC 103(a) over Mazza and Thorne is believed to be overcome and is requested to be withdrawn. If the Examiner does not find these comments to be persuasive, applicants would consider

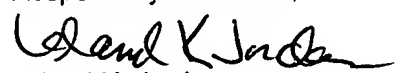
adding the limitation "wherein said period of time is less that a (storage) time required for said second aliquot portion to degrade".

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne et al (as applied to claims 1-4, 6 and 9-10 above, and further in view of the well known art, for example Boosalis et al (US 4362698, IDS) The Examiner cites Boosalis for disclosing using a protective film for covering the samples. Boosalis and the known prior art do not disclose providing bar code indicia on the original sample container to indicate a predetermined period of time for storing a second aliquot portion within a storage compartment and additionally testing the second aliquot specimen portion during said period of time as required by claim 1. Since claim 5 further limits claim 1, and since claim 1 is believed to be patentable over the prior art as discussed above, claim 5 is also believed to be patentable over Mazza in view of Thorne et al and further in view of the well known art, for example Boosalis. For these reasons, the Examiner's rejection of claim 5 as being unpatentable is believed to be overcome and is requested to be withdrawn.

Conclusion

Applicants believe that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicants' representative at the number provided below.

Respectfully submitted,



Leland K. Jordan
Registration No. 36,560
Agent for Applicant

DADE BEHRING INC.
1717 Deerfield Road, Box 778
Deerfield, IL 60015-778
Phone: (847) 267-5351